

REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance. The present amendment is being made to facilitate prosecution of the application.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-14 are currently pending. Claims 1, 10 and 11 are independent and are hereby amended. No new matter has been introduced. Support for this amendment is provided throughout the Specification as originally filed.

Changes to the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §101, §102, §103, or §112. Rather, these changes are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. EXAMINER INTERVIEW

Applicants' representative thanks the Examiner for granting the telephone interview on September 25, 2008. Applicants' representative presented the distinction between the present application and the Higo reference. The sheet member of the instant invention has the characteristic that it is not only permeable to the gel having the medicine but the permeability is sufficient to retain the gel in the iontophoresis device.

As understood by Applicants' representative, the Examiner contended the support (2) of *Higo* is *inherently* permeable to the gel. The Examiner pointed to *Higo* col. 3 lines 7-25, col. 3,

lines, 47-51, and col. 5, lines 34-40 as disclosing the support is permeable to the gel. The Examiner concluded this caused the present claim language to read on *Higo*.

In response, Applicants' representative argued that even accepting, *arguendo*, the support (2) of Higo is permeable to the gel, there is no disclosure in Higo of the support material being chosen to have a particular permeability, that is, sufficient for gel retention. Thus, even accepting the Examiner's inherency argument (which is not conceded), Higo still does not recognize nor place the limitation of restricting the permeability of the support to achieve the results of the present invention (*i.e.*, retention of the gel in the device).

No agreement was reached on claim language to overcome the *Higo* reference. However, the Examiner agreed to consider the arguments presented in the instant reply.

III. REJECTIONS UNDER 35 U.S.C. §102

Claims 1-7, 9-12, and 14 were rejected under 35 U.S.C. §102 as allegedly anticipated by U.S. Patent No. 6,259,946 to Higo et al. (hereinafter, merely Higo).

Applicants respectfully traverse this rejection.

Independent claim 1 is representative and recites, *inter alia*:

“a sheet member . . . having a property for allowing said gel to permeate therein,
...
wherein, when said gel is disposed on said sheet member in the region to receive the gel,
the property of the sheet member to allow the gel to permeate therein is sufficient to
provide a retention force resulting from a permeated portion of the gel to retain the gel in
the region to receive the gel.” (emphases added)

The Office Action asserts the un-amended “wherein” clause “does not impose any structural limitation upon the claim apparatus . . .” While Applicants disagree with the Office

Action, the claim language has been amended to make unmistakably evident that which was clear and inherent. In particular, the “wherein” clause characterizes the permeability of the sheet member to the gel containing the drug.

Thus, Applicants **have not** amended the claims in a manner inconsistent with the interpretation used in the Office Action. Applicants respectfully ask the amendment be entered so the application is in better form for appeal.

As understood by the Applicants, Higo discloses an iontophoresis device. The Office Action points to FIGS. 1-4 and identifies support (2) as corresponding to the sheet member of the present invention. However, Higo does not disclose that the support (2) has particular properties with respect to the permeability a gel containing a drug to be introduced into the body of a patient.

In contrast, claim 1 recites, “a sheet member . . . having a property for allowing said gel to permeate therein . . . wherein, when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to provide a retention force resulting from a permeated portion of the gel to retain the gel in the region to receive the gel.”

That is, the sheet member is made of a material that the gel containing the drug can permeate. The partial permeation of the gel into the sheet member creates a retention force between the gel and the sheet member. Pub. App. pars. [0023], [0024] and [0026]. Thus, the present invention claims a particular composition of the sheet member to have a recited permeability to gel in the area to receive the gel. The “wherein” clause characterizes the permeability property of the sheet member. That is, not only is the sheet member permeable to

the gel containing the drug, the extent of permeability is sufficient to retain the gel in the device. It is part of Applicants' invention to combine a sheet member into which a gel containing the drug can permeate as part of the iontophoresis device. This characteristic of the recited composition of the sheet member at least distinguishes the present iontophoresis device from that disclosed in Higo.

Thus, claim 1 is patentable over Higo because that reference does disclose each and every element recited in the claim. In particular, Higo does not disclose a sheet member covering the electrode layer with the sheet member "having a property for allowing said gel to permeate therein . . . wherein, when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to provide a retention force resulting from a permeated portion of the gel to retain the gel in the region to receive the gel" as recited in claim 1.

The Office Action at page 3 points to Higo, col. 3, lines 7-28, for disclosing the above sheet-member-permeability/gel-retention feature of claim 1. In particular, the Office Action states, "[i]t is noted that the sheet member serves to hold the electrolyte/gel and made of material with excellent workability, flexibly [sic] and suitable shape retention (col. 3, lines 7-9). Therefore, the retention force resulting from the permeated portion of the gel is sufficient to retain the gel in the region to receive the gel." This is a misreading and expansion of the teachings of Higo. There is no description of the permeability characteristic of the support (2) or electrolyte layer (3b). Certainly there is no discussion of a permeability characteristic with respect to the retention of gel containing the drug (6). *Higo*, FIG. 4.

The Office Action then concludes, “[t]herefore, the retention force resulting from the permeated portion of the gel . . .” as if this follows from the previous sentence. It does not. The Office Action asserts support (2) of Higo corresponds with the present application sheet member (50). However, the sheet member of the present application has specific characteristics recited in the claim. In particular, the sheet member has properties of (1) being permeable to the gel containing the drug, and (2) the extent of permeability is such that the portion of the gel that permeates into the sheet member creates a force sufficient to retain the gel in the device.

The support (2) of Higo is not characterized in terms of permeability or the extent of permeability of the gel containing the drug (6). The material for support (2) of Higo is only characterized as “material with excellent workability, flexibility and suitable shape retention and water retention . . . it is only necessary that the material have the effect mentioned above.” *Higo*, col. 3, lines 7-21. Certainly, there is no suggestion the support (2) is made of a material chosen to have permeability to a gel (6) sufficient to retain the gel containing the drug when a portion of the gel permeates therein. Any such suggestion would be sheer speculation.

Even accepting, *arguendo*, the support (2) of Higo is permeable to the gel, that would only be the first property (1) of the sheet member of the present invention, discussed above. A second property (2), the extent of permeability is not disclosed in Higo. There is no disclosure in Higo of the support material being chosen to have a particular permeability, that is, sufficient for gel retention. Thus, even accepting the support of Higo is permeable to the gel containing the drug (which is not conceded), Higo still does not recognize nor place the limitation of restricting the extent of that permeability to achieve retention of the gel in the device.

Further, the Office Action misunderstands the characteristics of support (2) of Higo with respect to allowing a gel (6) containing the drug to permeate therein. The material of the Higo device support (sheet member) is a popular polymer that does not have the property to allow the gel containing the drug to permeate therein. *Higo*, col. 3, lines 10-18. The electrolyte layer (3b) also is selected for electrical conductivity, not permeability to a gel containing a drug. *Higo*, col. 3, lines 22-28. In the Higo device, an electrolyte layer (3b) is only fitted into the concave portion of cup-shaped support (2). *Higo*, col. 2, lines 64-65 and FIG. 4.

Finally, the Office Action asserts, on page 4 (“Response to Arguments”) that Applicants have admitted that prior art teaches the claim 1 element, “a sheet member . . . having a property for allowing said gel to permeate therein . . . wherein, when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to provide a retention force resulting from a permeated portion of the gel to retain the gel in the region to receive the gel.” This just is not so. Note the present invention has an electrode (conductive) layer (30) and a sheet member (50) (on the conductive layer). The Background of the present invention describes only a conductive layer made of a porous material, with the drug contained in the porous material. There is no admission of a separate sheet member having the permeability as recited in the claims. Applicants request a specific citation for the Office Action contention of the alleged admission.

For reasons similar or somewhat similar to those described above with regard to independent claim 1, independent claims 10 and 11 are also believed to be patentable.

IV. REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 8 and 13 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Higo in view of U.S. Patent No. 6,731,987 to McAdams et al. (hereinafter, merely “McAdams”).

Applicants respectfully traverse this rejection.

Claims 8 and 13 depend from claims 1 and 11, respectively, and should be allowable for at least the same reasons as discussed above. McAdams does not add the feature missing from Higo.

V. DEPENDENT CLAIMS

The other claims are dependent from one of the claims discussed above and are therefore believed patentable for at least the same reasons. Because each dependent claim is also deemed to define an additional aspect of the invention, however, the individual reconsideration of the patentability of each on its own merits is respectfully requested.

CONCLUSION

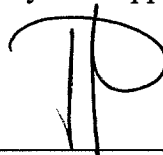
Claims 1-14 are in condition for allowance. In the event the Examiner disagrees with any of statements appearing above with respect to the disclosure in the cited reference, or references, it is respectfully requested that the Examiner specifically indicate those portions of the reference, or references, providing the basis for a contrary view.

Please charge any additional fees that may be needed, and credit any overpayment, to our Deposit Account No. 50-0320.

In view of the foregoing amendments and remarks, it is believed that all of the claims in this application are patentable and Applicants respectfully request early passage to issue of the present application.

Respectfully submitted,

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A handwritten signature in black ink, appearing to be 'P. Levy', written over a horizontal line.

By: _____

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